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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/758,142

01/15/2004

Noelle Mistretta

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EXAMINER

KHARE, DEVESH

ART UNIT

PAPER NUMBER

1623

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/758,142

Applicant(s)

MISTRETTA ET AL.

Examiner

Devesh Khare

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1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 11-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The applicant's election with traverse of Group I claims 1-10, 30 and 31 dated 02/22/2007 is acknowledged.

Response to Election with Traverse

Applicant's election with traverse of the aminated polysaccharide and a pharmaceutical composition thereof defined by Group I (claims 1-10, 30 and 31) is acknowledged. The traversal is on the ground(s) that "contrary to conventional reductive amination methods, the processes in claims 11 and 15 produce the derivatives of pneumococcus type 5 capsular polysaccharide with substantially increased immunogenicity and significantly without substantial amounts of compound X". This is not found persuasive because the examiner's restriction was based on product and process of making wherein applicants claims encompass two distinct classes of inventions: (1) an aminated polysaccharide and a pharmaceutical composition thereof, classes 514, 424 and 536, subclass various; and (2) a method for producing the aminated polysaccharide of Group I, class 536, subclass various.

It is noted that the reductive amination of carbohydrates by different procedures are well known in the art such as the conventional reductive amination procedure taught by Anderson (see previous office action). Therefore, the search for the claimed reductive amination procedures would be burdensome to the examiner as it cannot be assumed that the process claimed by the applicants is the only process for the reductive amination of a polysaccharide. The requirement is still deemed proper and is therefore made FINAL.

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Claims 11-29 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

An action on the merits of claims 1-10, 30 and 31 is contained herein below.

Objections

Claim 31 is objected to because of the following informalities:

Claim 31, depends on withdrawn claim 19. Therefore, claim 31 is not being examined on the merits.

Specification

The disclosure is objected to because of the following informalities:

The specification is objected to as failing to provide reference to the priority of the provisional application serial no. 60/442,154, filed 01/22/2003 and to the foreign priority of the France 0300488 filed 01/17/2003.

A certified copy of a claim of foreign priority is also required.

Appropriate correction is required.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 10, 30 and 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) Claim 1 contains the trademark/trade name CarbopacTM. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe particular column for the chromatography herein and, accordingly, the identification/description is indefinite.

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(2) Claims 1 and 3 are vague and indefinite. Claims 1 and 3 recite, the phrase "lacking a resonance" or "lacking a peak", it is unclear the identity of the missing resonance or the peak. What is missing? In absence of identity of a resonance in ^{13}C NMR between 13 and 14 ppm and a missing chromatogram peak between fucosamine and pneumosamine, claims 1 and 3 are vague and indefinite.

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 30 and 31 are rejected under 35 U.S.C. 103(a) as being obvious over Moreau (U.S. Patent 6,596,861) and Jansson et al. (Jansson) (Carb. Res., 1985).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the

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reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

It is noted that the ^{13}C NMR profile and chromatography profile of aminated pneumococcus type 5 capsular polysaccharide is claimed in the preamble of claims 1-4. In the aminated pneumococcus type 5 capsular polysaccharide claims, the said profiles are considered the inherent properties of aminated pneumococcus type 5 capsular polysaccharide, does not have any patentable weight towards the claimed compound. Also, how said compounds are produced does not have any patentable weight towards the claimed compound.

Moreau teaches a method for the reductive amination of polysaccharide useful in a process for conjugating polysaccharides to polypeptides (col.1, lines 1-4). Moreau discloses the aminated capsular polysaccharide of *Streptococcus pneumoniae* of serotype 5 (col.6, lines 60-61). Regarding claims 10, 30 and 31, the prior art discloses that the aminated polysaccharide can be conjugated to a polypeptide per se (col.8, lines 60-61). Moreau also discloses the reductive amination of acidic (negatively charged) polysaccharide (col.10, Example 1). Moreau discloses the pharmaceutical composition of said compounds and their conjugates thereof (col.10, lines 24-29). The prior art is silent in disclosing specifically the expanded formula which corresponds to pneumococcus type 5 capsular polysaccharide.

Jansson teaches the repeating-unit structure of *Streptococcus pneumoniae* type 5 capsular polysaccharide composed of glucose, N-acetylated fucosamine, N-acetylated

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pneumosamine (2-acetamido-2,6-deoxytalose), glucuronic acid and Sug (2-acetamido-2,6-deoxyhexose-4-ulose) (page 101, abstract). Jansson discloses the ^1H and ^{13}C -nmr spectra to characterize the polysaccharide structure (page 103, fig.1 and page 107). Jansson also discloses borohydride reduction of *Streptococcus pneumoniae* type 5 capsular polysaccharide to obtain the product having similar immunological activity, which can also be used as a vaccine (page 107, last para. to page 108, lines 1-3; page 108, last para.).

With regard to claims 5-9, wherein the repeating units are 90% and 95%; and A is represented by C=O or CHOH, it would be within the scope of the artisan in this art to optimize them through routine experimentation of reductive amination of a polysaccharide in view of cited prior arts.

It would have been obvious to person having ordinary skill in the art at the time the invention was made to accomplish aminated pneumococcus type 5 capsular polysaccharide and a pharmaceutical composition thereof, because Moreau teaches a method for the reductive amination of polysaccharide useful in a process for conjugating polysaccharides to polypeptides; and Jansson teaches reduced *Streptococcus pneumoniae* type 5 capsular polysaccharide. The motivation is provided by Moreau, the prior art suggests that reductive amination of a polysaccharide of interest provides the product retaining essential antigenic determinants within the polysaccharides which is extremely important in the preparation of a conjugate vaccines having the essential structure and conformation of the component materials (col.2, lines 57-64).

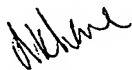
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Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0627. The official fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Devesh Khare, Ph.D., J.D.
Art Unit 1623

March 19, 2007